K062894

FEB 8 2007

510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA and 21 CFR §807.92

1.0 Submitter's Indentification:

Submitter's Name:	DailyCare BioMedical Inc.
Address:	8F, 25-3, Ji-Lin Road, Chungli 320, Taiwan
TEL:	*+886-3-2621688*
FAX:	*+886-3-2617688*
Contact:	Mr. Daniel J. H. Chang

2.0 Device Name:

Trade Name:	InstantCheck RTD-ECG Monitor
Common Name:	Handheld ECG monitor
Classification Name:	Electrocardiograph (per 21 CFR 870.2340)

3.0 Classification: Class II

4.0 Predicate Device: ReadMyHeart (RMH2.0) (K042814)
Omron HCG-801 Portable ECG Monitor (K060766)

5.0 Intended Use:

The InstantCheck RTD-ECG monitor is a personal single lead electrocardiographic monitor which the ECG acquisition and transmission can be voluntarily and mutually activated by the adult users for the purpose of healthcare management and reference for healthcare professionals.

The user presses his/her thumbs on the electrodes in order to record the ECG signal. The users may also record the signals optionally through auxiliary external electrode provided separately if thumb pressing is not convenient for reason.

6.0 Indications for Use:

The InstantCheck RTD-ECG monitor is a personal single lead electrocardiographic monitor for recording and displaying real-time ECG data for home health care use. This device is intended for self-testing by adult users who might experience transient symptoms that may suggest cardiac conduction abnormity or by adult users whenever they want to have routine checks.

ECG acquisition and transmission can be voluntarily and mutually activated by the adult users for the purpose of healthcare management and reference for healthcare professionals.

The user is normally not required to apply electrode on body. Two electrodes integrated within the device are provided. The user has to press his/her thumbs on the electrodes in order to record the ECG signal. The users may also record the signals optionally through auxiliary external electrode provided separately if thumb pressing is not convenient for reason. The recorded data can be downloaded to Personal Computer via USB interface port.

7.0 Device Description:

The InstantCheck RTD-ECG monitor is a new model of handheld ECG monitors series of DailyCare BioMedical Inc. InstantCheck RTD-ECG is a handheld, personalized use, dry electrode and affordable ECG recording device that records user's cardiac functions and displays the data in a clear and precise waveform for daily health check. It takes ECG signals of users by thumbs pressing gently on electrodes which are integrated on the device. InstantCheck RTD-ECG can record real-time display the user's ECG data for about 30 seconds, and automatically store the last 15 seconds signals into the build-in memory. While three parameters were measured, mainly, Heart Rate (HR), ST segment and QRS interval of cardiac ECG signal, will be displayed on LCD display of the device.

User may also record ECG data optionally through auxiliary external electrode provided separately, if thumb pressings are inconvenient for any reason. The data stored in the memory can be transferred to Personal Computer via USB. With friendly

GUI software provided separately, data stored in InstantCheck RTD-ECG can be printed for analysis, and for long-term tracking. InstantCheck RTD-ECG is powered by internal battery source. Users may activate the device to acquire ECG Lead I information voluntarily and mutually.

InstantCheck RTD-ECG is not intended for use as a substitution of precise diagnostic tool. This device is also not intended for recording and transmission of user's ECG signal simultaneously. Users with implanted pacemaker are not recommended to use this device.

8.0 Non-Clinical Performance Summary:

In terms of operating specification, Safety & EMC requirements, the device conforms to applicable standards including

* Electrical Safety test according to IEC 60601-2-25 & IEC 60601-1,
* EMC tests according to IEC 60601-1-2
* Performance tests according to IEC 60601-2-47 and IEC 60601-2-51.
* Environment tests are tested to comply with the safety requirements.
*The performance is also tested with MIT-IBH database and simulators.

9.0 Discussion of Clinical Test performed:

InstantCheck RTD-ECG has the same fundamental scientific technology as the original cleared device, ReadMyHeart. Clinical validation for ECG parameters is not required.

10.0 Conclusions:

In order to benefit the public health and healthcare professionals, the InstantCheck RTD-ECG has simple, friendly software user interface. It has similar technological characteristics as previously cleared ReadMyHeart. The InstantCheck RTD-ECG demonstrates essential safety and effective to the users.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 8 2007

DailyCare BioMedical Inc.
c/o Mr. Daniel J.H. Chang
8F, 25-3, Ji-Lin Road
Chungli 320, Taiwan

Re: K062894
Trade Name: InstantCheck RTD-ECG Monitor, Model RMH4.0
Regulation Number: 21 CFR 870.2340
Regulation Name: Electrocardiograph
Regulatory Class: Class II
Product Code: DPS
Dated: September 27, 2006
Received: January 9, 2007

Dear Mr. Chang:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K062894

Device Name: InstantCheck RTD-ECG monitor
(DailyCare BioMedical Inc.)

Indications for Use:

The InstantCheck RTD-ECG monitor is a personal single lead electrocardiographic monitor for recording and displaying real-time ECG data for home health care use. This device is intended for self-testing by adult users who might experience transient symptoms that may suggest cardiac conduction abnormity or by adult users whenever they want to have routine checks.

ECG acquisition and transmission can be voluntarily and mutually activated by the adult users for the purpose of healthcare management and reference for healthcare professionals.

The user is normally not required to apply electrode on body. Two electrodes integrated within the device are provided. The user has to press his/her thumbs on the electrodes in order to record the ECG signal. The users may also record the signals optionally through auxiliary external electrode provided separately if thumb pressing is not convenient for reason. The recorded data can be downloaded to Personal Computer via USB interface port.

Prescription Use ✓ AND/OR Over-The-Counter Use ____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

[signature]
Division Sign-Off)
Division of Cardiovascular Devices
(510(k) Number K062894